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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,857	11/07/2000	Kathryn Armour	620-117	5675

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,857	ARMOUR ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29,31-33,37-42 and 46-70* is/are pending in the application.

4a) Of the above claim(s) *31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,25,28,29,32,41,55,56,59,62,63,66 and 67* is/are rejected.

7)☒ Claim(s) *16-20,23,24,26-27, 33, 37-40, 42, 46-54,57,58, 60-61, 64, 65 and 68-70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 16-29, 31-33, 37-42, and 46-70 are pending.

2. Claim 31 stands withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.

3. A telephone call was made to applicants' representative Mary J Wilson on at least two separate occasions August 31, 2006 and December 14, 2006 to advance prosecution of this case to allowance since the only issues remain in the case are objection and 112-second paragraph issues. However, Applicants' representative wishes to receive a written communication rather than oral communication.

4. The following objection and new grounds of rejections are necessitated by the amendment filed 10/4/06.

5. Applicant is advised that should claims 55-56 be found allowable, claims 66-67 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. Claims 20 and 54 are objected to because of the following informality: "A host cell" should have been "An isolated host cell". Appropriate correction is required.

7. Claim 23 is objected to because said claim fails to conform with current U.S. practice. It is suggested that Claim 23 be amended to recite "A method of binding a target molecule wherein the method comprises said target molecule with the binding molecule of claim 32 under condition to allow binding. Appropriate correction is required.

8. Claims 24 and 58 are objected to because of the following informality: The ":" should have been deleted. Appropriate correction is required.

9. Claim 38 is objected to because of the following informality: "...target molecule selected..." should have been "....target molecule **is** selected...". Appropriate correction is required.

10. Claim 47 is objected to because of the following informality: "is" is missing between "molecule selected". Appropriate correction is required.

11. Claim 57 is objected to because said claim fails to conform with current U.S. practice. It is suggested that Claim 57 be amended to recite "A method of binding a target molecule wherein the method comprises said target molecule with the binding molecule of claim 41 under conditions to allow binding." Appropriate correction is required.

12. Claim 61 is objected to because of the following informality: "selected from:" should have been "selected from the group consisting of". Appropriate correction is required.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

14. Claims 21-22, 25, 28-29, 32, 41, 55-56, 59, 62, 63, and 66-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "...**2**, 3 or 4 amino acids in at least 1 region of the CH2 domain..." in claim 21, at line 17 is indefinite and fails to provide antecedent basis for the following blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S. The specification at page 10, lines 21-22 discloses "these substitutions are made in 'block' of 233-236 *and/or* 327, 330, 331. Substitution in block of 233-236 means there are four amino acids substitution. Substituting in block 327, 330 and 331 means there are three amino acid substitution. As such, it is not clear substituting which block(s) would result in "2" amino acid substitutions. It is suggested that applicant substituting the term "2" be canceled.

The "wherein said chimeric CH2 domain is at least **98%** identical to a CH2 sequence (residues 231-340) from human IgG1 or IgG4 having said modified amino acids" in claim 21 (beginning at page 4 of the amendment to the claims) is indefinite because after substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S as recited in claim 21, the sequence identity is 93.7% rather than 98%. One of ordinary skill in the art cannot appraise

the metes and bound of the claimed invention. It is suggested that the phrase "wherein said chimeric CH2 domain is at least **98%** identical to a CH2 sequence (residues 231-340) from human IgG1 or IgG4 having said modified amino acids" be deleted.

The term "wherein **2 amino acids** in 1 region of the CH2 domain ..." in claim 22, line 1 is ambiguous and indefinite because The specification at page 10, lines 21-22 discloses "these substitutions are made in 'block' of 233-236 *and/or* 327, 330, 331. It is suggested that claim 22 be canceled.

The terms "prevent" and "otherwise" in claims 25 and 59 should be deleted.

The term "wherein said *contacting is effected* in a patient" in claim 28 has no support in base claim 23. It is suggested that claim 28 be amended to recite "The method of claim 23 wherein said target molecule is in patient...".

The "administered to a patient, or optionally in case where the patient is an unborn infant, to the mother or the patient" in claim 29 lacks antecedent basis in base claim 23. The term "administered" is not recited in claim 23. It is suggested that claim 29 be amended to recite "The method of claim 23 wherein the contacting step is a step of administering to a patient, or optionally to the mother of the patient in cases where the patient is an unborn infant."

The phrase ", and is at least **98%** identical to a CH2 sequence (residues 231-340) from human IgG1 or IgG4 having said modified amino acids" in claim 32 at line 19 is indefinite because after substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S as recited in claim 32, the sequence identity is 93.7% rather than 98%. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention. It is suggested that the phrase ", and is at least **98%** identical to a CH2 sequence (residues 231-340) from human IgG1 or IgG4 having said modified amino acids" be deleted.

Likewise, the phrase "...is at least **98%** identical to a CH2 sequence (residues 231-340) from human IgG1 or IgG4 having said modified amino acids" in claim 41 at the last two lines is indefinite because after substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S as recited in claim 32, the sequence identity is 93.7% rather than 98%. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention. It is suggested that the phrase ", and is at least **98%** identical to a CH2 sequence (residues 231-340) from human IgG1 or IgG4 having said modified amino acids" be deleted.

The term "...**2**, 3 or 4 amino acids in at least 1 region of the CH2 domain..." in claims 55 and 66 at line 17 is indefinite and has no antecedent basis for the following blocks of amino acid

at 233P, 234V, 235A, no and no residue at 236 and 327G, 330S and 331S. The specification at page 10, lines 21-22 disclose "these substitutions are made in 'block' of 233-236 *and/or* 327, 330, 331. Substitution in block of 233-236 means there are four amino acids substitution. Substituting in block 327, 330 and 331 means there are three amino acid substitution. As such, it is not clear substituting which block(s) would result in "2" amino acid substitutions.

The phrase "...wherein said chimeric C_H2 domain is least **98%** identical to a C_H2 sequence (residues 231-340) from human IgG1 or IgG2 having said modified amino acids" in claim 55 and 66 is indefinite because after substituting the blocks of amino acid at 233P, 234V, 235A, 236G, 327G, 330S and 331S as recited in claim 32, the sequence identity is 93.7% rather than 98%. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention. It is suggested that the phrase ", and is at least **98%** identical to a C_H2 sequence (residues 231-340) from human IgG1 or IgG2 having said modified amino acids" be deleted.

The phrase "wherein **2** amino acids" in claims 56 and 67 is indefinite and ambiguous. This is because substitution in block of 233-236 means there are four amino acids substitution. Substituting in block 327, 330 and 331 means there are three amino acid substitutions. As such, it is not clear substituting which block(s) would result in "2" amino acid substitutions.

The term "wherein said *contacting is effected* in a patient suffering from" in claim 62 has no support in base claim 57. It is suggested that claim 62 be amended to recite "The method of claim 57 wherein said target molecule is in patient..."

The term "wherein the binding molecule is administered to a patient, or optionally in cases where the patient is an unborn infant, to the mother of the patient" in claim 63 lacks antecedent basis in base claim 57. The term "administered" is not recited in claim 57. It is suggested that claim 63 be amended to recite "The method of claim 57 wherein the contacting step is a step of administering to a patient, or optionally to the mother of the patient in cases where the patient is an unborn infant."

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9: 00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

18. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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